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Title: Access to biologicals in Crohn's disease in ten European countries

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1 What did this study explore?

This study explores three different dimensions of access to biologicals (originators and biosimilars) for Crohn's disease, namely availability, affordability and acceptability in ten selected European countries (the Czech Republic, France, Germany, Hungary, Latvia, Poland, Romania, Slovakia, Spain and Sweden). We also explore whether differences in availability and affordability of biologicals are associated with the uptake of biologicals (in terms of number of patients on biologicals per 100000 population), and the economic situation of the country or the financing of the health care systems.

2 How did the authors perform all experiments?

A questionnaire was developed to collect information on access to biologicals and was sent in May 2016 to one expert (gastroenterologist) in each of the ten European countries included in the study, i.e. the Czech Republic, France, Germany, Hungary, Latvia, Poland, Romania, Slovakia, Spain and Sweden. The questionnaire was developed based on questionnaires used in prior studies in rheumatoid arthritis of Putrik

¹ This is not really an observational study as no patients were involved. This was a questionnaire survey, data were collected via experts, who provided country-level data on access.

et al. The country experts who were invited to fill in the questionnaire, were selected based on the principle of non-probability convenience sampling, which resulted in a sample drawn through the professional network of the researchers.

Reference:

Putrik P, Ramiro S, Kvien TK, Sokka T, Pavlova M, Uhlig T, Boonen A. Inequities in access to biologic and synthetic DMARDs across 46 European countries. *Ann Rheum Dis* 2014; 73(1): 198-206 [PMID: 23467636 DOI: 10.1136/annrheumdis-2012-202603]

3 How did the authors process all experimental data?

Data were extracted from the questionnaires. The returned questionnaires were checked and in case of missing or incomplete answers, the collaborating experts were contacted to clarify the information. Finally, a preliminary report including the results was sent to all collaborating experts for a review and data check.

The questionnaire-based survey was combined with desk research, where relevant indicators, such as countries' gross domestic product (GDP) and population size, was identified. The number of CD patients on biologicals was extracted from resources provided by the collaborating experts or was calculated from the total number of CD patients and the estimated share of CD patients on biologicals. Furthermore, drug prices and other data derived from the questionnaires, were also checked during the desk research.

The correlation analysis was carried out using Stata Data Analysis and Statistical Software version 12 (© Copyright 1996–2017 StataCorp LLC).

4 How did the authors deal with the pre-study hypothesis?

The pre-study hypothesis that the number of Crohn-patients on biologicals per 100000 population correlates with the economic development of the country, the availability and affordability of biologicals was confirmed during the study.

5 What are the novel findings of this study?

Regarding availability, reimbursement criteria were the least strict in Sweden and Germany, and the strictest in Hungary, Poland and Slovakia.

Regarding affordability, between countries, the annual cost of different biological treatments differed 1.6–3.3-fold. Treatments were the most affordable in Sweden (13-37% of the GDP per capita) and the least affordable in the Central and Eastern European countries, especially in Hungary (87-124%) and Romania (141-277%).

The number of patients with Crohn's disease on biologicals per 100000 population was strongly correlated with GDP per capita (0.91), although substantial differences were found in the uptake among countries with similar economic development.

Correlation between the number of patients with Crohn's disease on biologicals per 100000 population and the availability and affordability was also strong (-0.75,-0.69 respectively).